



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification⁴ : A61J 3/10, A61K 9/44	A1	(11) International Publication Number: WO 89/ 05624 (43) International Publication Date: 29 June 1989 (29.06.89)
(21) International Application Number: PCT/US88/04367 (22) International Filing Date: 12 December 1988 (12.12.88) (31) Priority Application Number: 134,006 (32) Priority Date: 17 December 1987 (17.12.87) (33) Priority Country: US (60) Parent Application or Grant (63) Related by Continuation US 134,006 (CON) Filed on 17 December 1987 (17.12.87) (71) Applicant (for all designated States except US): THE UPJOHN COMPANY [US/US]; 301 Henrietta Street, Kalamazoo, MI 49001 (US).		(72) Inventors; and (75) Inventors/Applicants (for US only) : NI, Phillip, F. [US/ US]; 10557 West P Avenue, Mattawan, MI 49071 (US). ODAR, Larry, F. [US/US]; 9646 Treetop Drive, Galesburg, MI 49053 (US). (74) Agent: JAMESON, William, G.; Patent Law Depart- ment, The Upjohn Company, Kalamazoo, MI 49001 (US). (81) Designated States: AT (European patent), AU, BE (Eu- ropean patent), CH (European patent), DE (Euro- pean patent), DK, FI, FR (European patent), GB (European patent), IT (European patent), JP, KR, LU (European patent), NL (European patent), NO, SE (European patent), US. Published <i>With international search report.</i>
(54) Title: TRI-SCORED DRUG TABLET <div style="text-align: center;"> </div>		
(57) Abstract <p>A tri-scored drug tablet (10) having an elongated tablet body (11) with a length greater than its width. The body (11) has a bottom facing surface with a pair of concavities (23, 24) therein. Each concavity (23, 24) is equal in size and has parallel major and minor axes, each concavity (23, 24) further having a smooth and uninterrupted arcuate surface extending between the opposite longitudinal ends of said body (11) and a longitudinally central part of said tablet (10). The opposite longitudinal ends of the body (11) and the longitudinally central part are of a thicker dimension than the thickness of the body (11) measured at an apex of each of the concavities (23, 24). Aligned breaking grooves (21, 29, 31, 32) are formed in the top and bottom surfaces at both of the concavities (23, 24) and between the concavities (23, 24) at said longitudinally central part, each of breaking groove (21, 29, 31, 32) extending laterally across the width of said tablet (10) at said apex of each of said concavities (23, 24) at said longitudinally central part to divide the tablet (10) into four quarter sections (48, 49, 51, 52) of equal size.</p>		

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- 1 -

TRI-SCORED DRUG TABLET

FIELD OF THE INVENTION

This invention relates to a tri-scored drug tablet and, more particularly, to a tri-scored drug tablet having a length greater than its width and structure for facilitating a breaking of the tablet into four equal parts.

BACKGROUND OF THE INVENTION

Scored drug tablets have been known for many years and are provided to patients to enable them to break the tablet into two or more parts to enable fractional dosages of the medicine to be taken by the patient (see British Patent No. 993 291). Heretofore, problems have been encountered by the patient in facilitating a proper breakage of the tablet into its component parts due to the strength of the binder agents utilized to bind the active pharmacological agents contained within the tablet. Arthritic patients may be unable to break the tablet into its component parts due to the aforesaid strength characteristic. In some instances, a sharp edged tool, such as a knife, is needed in order to effect an even breakage of the tablet into its component parts. Further, and more important, is the requirement

- 2 -

that the fractured tablet components contain the corresponding fraction, within the required $\pm 15\%$ limits, of active pharmacological agents in each of the divided sections.

5 It is an object of the present invention to provide a tri-scored drug tablet capable of being easily broken into four parts.

It is a further object of this invention to provide a tri-scored drug tablet, as aforesaid, capable of being
10 broken into its component parts by simply holding the tablet between the thumb and forefinger and applying the requisite compressive breaking force.

It is a further object of this invention to provide a tri-scored drug tablet, as aforesaid, which has a length
15 greater than its width and appropriate structure at its opposite longitudinal ends and longitudinally central part as well as structure defining a zone of weakness at the longitudinally central part and in the central region of each half section to facilitate a breakage of the tablet
20 into separate but equal components.

It is a further object of this invention to provide a tri-scored drug tablet, as aforesaid, having the requisite strength characteristics to prevent premature breakage of the tablet either during manufacture, insertion into a
25 container or during transit of the container to the end user.

It is a further object of this invention to provide a tri-scored drug tablet, as aforesaid, which is easy to manufacture and is of sufficient but yet minimum size to
30 facilitate easy swallowing of the tablet by the end user patient.

SUMMARY OF THE INVENTION

The objects and purposes of the broadest aspect of the invention, including those set forth above, are met by
35 providing a tri-scored drug tablet having an elongated

- 3 -

tablet body with a length greater than its width. The tablet body also has a bottom surface with a pair of concavities being provided therein. Aligned breaking grooves are formed in the top and bottom surfaces. The breaking grooves in the bottom surface are provided in both of the concavities as well as at a longitudinally central part and extend laterally across the width of the tablet at an apex of each cavity and at the longitudinally central part. Thus, upon a user grasping both ends of the tablet between a forefinger and a thumb on each hand, a force is applied to effect a fracture of the tablet along the breaking groove at the longitudinally central part to divide the tablet into two half sections, the user thereafter placing the two half sections in a stacked arrangement so that the two concavities face one another and the thickest dimensioned portions at the longitudinal ends of the half sections are in engagement, the user thereafter applying a compressive force to the midpoint of the stacked half sections to effect a fracture of each of the halves along the breaking grooves at the apexes of the concavities to divide each of the half sections into two quarter sections.

BRIEF DESCRIPTION OF THE DRAWING

The subject matter of the invention will be described in more detail hereinafter in connection with the exemplary embodiments illustrated in the drawing, in which:

Figure 1 is a left top perspective view of a tri-scored tablet embodying the invention;

Figure 2 is a left bottom perspective view of the tablet;

Figure 3 is a top view thereof;

Figure 4 is a bottom view thereof;

Figure 5 is a side view thereof;

Figure 6 is an end view thereof;

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- 4 -

Figure 7 is a sectional view taken along the line VII-VII of Figure 3;

Figure 8 is a sectional view taken along the line VIII-VIII of Figure 3;

5 Figure 9 is a side view similar to Figure 5 but with the tablet separated into two half sections;

Figure 10 is a side view of a half section resting on a support surface;

10 Figure 11 is a side view of two half sections, one stacked on the other;

Figure 12 is a side view of the stacked half sections following the application of force causing a simultaneous breakage of each half section into two quarter sections;

15 Figure 13 illustrates a half section having an arcuate end, so that the opposing ends of the half sections will engage along a line;

Figure 14 illustrates a half section having a flat end surface, so that the opposing ends of the half section will engage along or at opposing flat surfaces; and

20 Figure 15 illustrates a half section having a pair of laterally spaced pads with flat surfaces, so that the opposing ends of the half sections will engage at the opposing pads.

DETAILED DESCRIPTION

25 A tri-scored drug tablet 10 is illustrated in a perspective view in Figures 1 and 2. Figure 1 illustrates the drug tablet from the top and left end thereof. Figure 2 illustrates the drug tablet from the bottom and left end thereof. The tablet 10 has an elongated tablet body 11 having a length greater than its width. The tablet body includes an elongated central body part 12 of a finite and uniform thickness and having an outwardly facing, smooth and uninterrupted perimetrical surface 13 extending parallel to a theoretical line 14 (Figure 3) extending
30 through a geometric center of the tablet and parallel to
35

- 5 -

the section line VIII-VIII in Figure 5. Further characteristics of the theoretical line will be explained in more detail below. The central body part 12 is generally of an oblong, almost rectangular shape with rounded corners as shown in Figures 3 and 4. Further, the central body part 12 has a flat top surface 16 and a flat bottom surface 17.

The top surface 16 of the central body part 12 has a layer 18 of material of uniform thickness provided thereon along the length thereof. The upper peripheral edges of the layer 18 are rounded as at 19. Three laterally extending scores or breaking grooves 21 are provided in the layer 18 at equidistantly spaced intervals along the length of the tablet to divide the layer 18 into four equal sections. The upper surface of the layer 18 is flat and parallel to the surface 16. The scores or breaking grooves 21 have a depth that is approximately one fourth to one half the thickness of the layer 18, preferably one third the thickness. Further, the breaking grooves have an arcuate contour conforming to the rounded peripheral edge at both ends of the breaking grooves. The included angle θ between the sidewalls of the breaking grooves 21 is in the range of 70° to 110° , preferably 90° .

The bottom surface of the central body part 12 has a layer 22 of material provided thereon along the length thereof. Into the bottom facing surface of the layer 22 there is provided a pair of arcuately contoured concavities 23 and 24. The provision of the arcuately contoured concavities 23 and 24 in the bottom facing surface of the layer 22 leaves three raised surface portions 26, 27 and 28 at the opposite longitudinal ends of each concavity. The downwardly facing surface of each arcuately contoured concavity 23 and 24 is smooth between the raised surfaces 26, 27, and 27, 28 except for the provision of a breaking groove 29 in the concavity 23 and a breaking groove 31 in the concavity 24. Each breaking groove 29 and 31 extends

- 6 -

laterally of the tablet in a direction perpendicular to the longitudinal axis of the drug tablet 10. Further, the breaking grooves 29 and 31 are both located at the apex of the arcuately contoured concavities 23 and 24 and the depth of each groove extends to but not beyond the bottom surface 17 of the central body part 12 as illustrated in Figure 5.

The raised surface portion 27 in the central region of the bottom facing surface also has a breaking groove 32 therein that extends laterally of the tablet parallel to the breaking grooves 29 and 31. The breaking groove 32 divides the raised surface portion 27 into two raised parts 33 and 34 of equal proportion. The breaking groove 32 has a depth such that the apex of the V-like bottom is spaced approximately .005 inches from the bottom surface 17 of the central body part 12 as illustrated in Figure 5. The included angle ϕ (Figure 9) between the sidewalls of the breaking grooves 29 and 31 is in the range of 70° to 110° , preferably 90° . The included angle α (Figure 5) between the sidewalls of the breaking groove 32 is in the range of 60° to 100° , preferably 80° .

Each of the three breaking grooves 29, 31 and 32 are aligned with a respective one of the three breaking grooves 21 so that vertical cutting planes perpendicular to the longitudinal axis of the tablet and extending through each aligned pair of breaking grooves 21, 29; 21, 32; and 21, 31 will divide the tablet into four equal sections 36, 37, 38 and 39.

When the tablet 10 is placed so that the raised surface portions 26 and 28 rest on a flat surface 41 (Figure 5), a gap or spacing X exists between the raised parts 33 and 34 and the flat surface 41. This space or gap is insufficient, however, for facilitating a fracturing of the tablet along the aligned breaking grooves 21, 32 when a force is applied to the upper surface of the layer 18 at the central breaking groove 21.

- 7 -

The spacing between the bottom of each of the breaking grooves 21 and the bottom of the aligned one of the breaking grooves 29, 31 and 32 define a zone of weakness generally referred to by the reference numerals 42, 43 and 44. A cross section of the zones of weakness 42 and 43 are shown in Figures 7 and 8. Thus, when the tablet is grasped by a user between the thumb and forefinger of each hand, an appropriate force can be applied to effect a fracturing of the tablet along the zone of weakness 43, namely, along a plane defined by the aligned breaking grooves 21 and 32. This is schematically represented in Figure 9. Following a separating of the tablet 10 into two half sections 46 and 47, one of the half sections, such as the half section 46 in Figure 10, can be positioned so that the raised surfaces 26 and 33 rest on a supporting surface 41. In other words, the concavity 23 faces the supporting surface 41. A pencil or finger of the user can then be used to apply a force in direction of the arrow P to the aligned breaking grooves 21 and 29 to effect a fracturing of the half section into two quarter sections 48 and 49.

In the alternative, the half sections 46 and 47 can be simultaneously fractured into quarter sections utilizing a different methodology. For example, and referring to Figure 11, the half sections 46 and 47 are positioned so that the raised surfaces 26 and 33 engage respectively the raised surfaces 28 and 34. In other words, the concavities 23 and 24 face one another. In addition, the aligned set of breaking grooves 21 and 29 on the half section 46 are parallel to and congruent with the aligned set of breaking grooves 21 and 31 on the half section 47. A placement of this stacked arrangement between the thumb and forefinger of a user's hand will, upon the application of a compressive or pinching force in the direction of the arrows F and

- 8 -

T will effect a simultaneous fracturing of the half sections 46 and 47 into four quarter sections 48, 49, 51 and 52.

During each of the aforementioned fractures, a fracturing of the tablet 10 into half sections 46 and 47 results in the tablet having the requisite active pharmacological agents in each half and within the requisite limits of $\pm 15\%$. Similarly, a fracturing of the half sections 46 and 47 into quarter sections also results in each quarter section having the requisite active pharmacological agent within the prescribed $\pm 15\%$ limit.

Figures 13 to 15 illustrate a half section, such as the half section 46. In order to differentiate between each of the half sections illustrated in these figures, the reference numeral 46 has been utilized to identify the half section in Figure 13 whereas the suffix "A" and "B" have been added to the reference numeral 46 in Figures 14 and 15. In the embodiment illustrated in Figure 13, a pair of lines 53 and 54 are illustrated and represent the lines whereat engagement of the half section 46 occurs with either a flat surface 41 or the other half section 47 when in a stacked arrangement, such as is illustrated in Figure 11. Both half sections would, therefore, engage at lines congruent with the lines 53 and 54 illustrated in Figure 14.

In the embodiment of Figure 14, the half section 46A has a pair of flat surface areas 56 and 57 thereon. Thus, the half section 46A can be oriented so that the flat surfaces 56 and 57 rest on the flat surface 41 or corresponding flat surfaces of the other half section when the half sections are positioned in a stacked arrangement, such as illustrated in Figure 11.

In the embodiment illustrated in Figure 15, four surface pads 58, 59, 60 and 61 are provided at the raised surface portions 26 and 27. The surface pads 58 are flat

surfaces that are raised above the upper most height of the raised surface portions 26 and 27. Thus, the surface pads 58, 59, 60 and 61 will rest on a flat surface when the half section is placed in the position illustrated in Figure 10.

5 Similarly, the aforementioned surface pads will rest on corresponding surface pads of the other half section when the half sections are stacked in the arrangement such as illustrated in Figure 11.

10 Although particular preferred embodiments of the invention have been disclosed in detail for illustrative purposes, it will be recognized that variations or modifications of the disclosed tablet lie within the scope of the present invention.

- 10 -

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. A tri-scored drug tablet, comprising:
 - 5 an elongated tablet body having a length greater than its width, said body having top and bottom surfaces;
a pair of concavities in said bottom surface, said top surface being flat, each concavity being equal in size and having parallel major and minor axes, each concavity
 - 10 further having a smooth and uninterrupted arcuate surface extending between the opposite longitudinal ends of said body and a longitudinally central part of said tablet, said opposite longitudinal ends of said body and said longitudinally central part being of a thicker dimension than
 - 15 the thickness of said body measured at an apex of each of said concavities;
aligned breaking groove formed in said top and bottom surface at both of said concavities and between said concavities at said longitudinally central part, each said
 - 20 breaking groove extending laterally across the width of said tablet at said apex of each of said concavities and at said longitudinally central part, so that upon a user grasping both ends of said tablet between a forefinger and a thumb on each hand, a force is applied to effect a
 - 25 fracture of said tablet along said groove at said longitudinally central part to divide said tablet into two half sections, said user thereafter placing said two half sections in a stacked arrangement so that said two concavities face one another and said thicker dimensioned
 - 30 portions at the longitudinal ends of said half sections are in engagement, said user thereafter applying a compressive force to the midpoint of said stacked half sections to effect a simultaneous fracture of each of said halves along said breaking grooves at said apexes of said concavities
 - 35 to divide each of said half sections into two quarter sections.

- 11 -

2. The tri-scored drug tablet according to Claim 1,
wherein said tablet body includes an elongated central body
part of a finite and uniform thickness and having an
outwardly facing, smooth and uninterrupted perimetrical
5 surface extending parallel to a theoretical line perpen-
dicular to said top surface and extending through a
geometric center of said tablet, wherein each said thicker
dimensioned portions at each end of said bottom surface of
each half section of said central body part is defined by
10 an upstanding surface part between which is provided said
concavity, the depth of each of said concavities being less
than the highest height dimension of said surface parts;

wherein said breaking grooves in said concavities and
at said longitudinally central part of said bottom surface
15 has a depth that extends from said apex of each of said
concavities to a bottom surface of said central body part;
and

wherein each of said breaking grooves in said top
surface has a depth that extends approximately one fourth
20 to one half the distance between said top surface and a top
surface of said central body part.

3. The tri-scored drug tablet according to Claim 2,
wherein said breaking grooves in said top surface extend
25 one third the distance between said top surface and said
top surface of said central body part.

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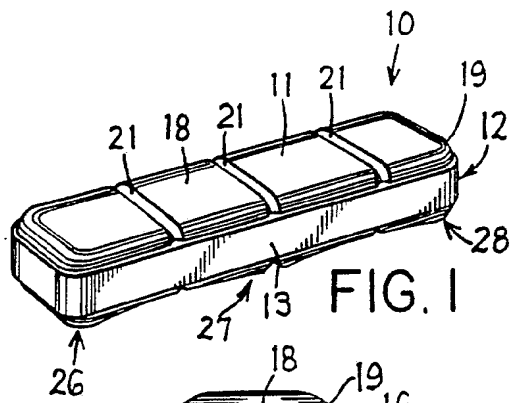


FIG. 1

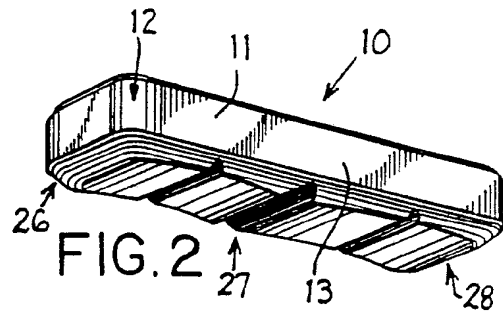


FIG. 2

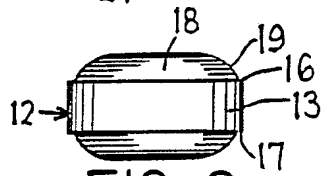


FIG. 6

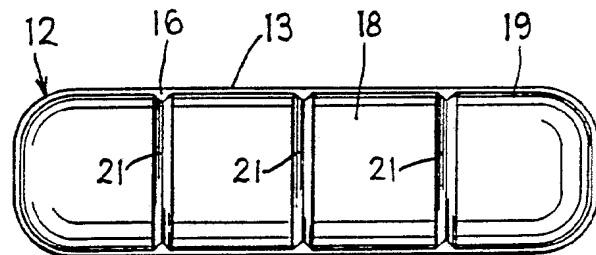


FIG. 3

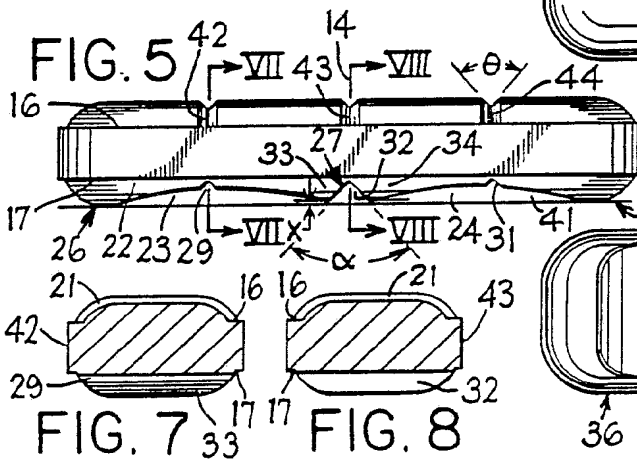


FIG. 5

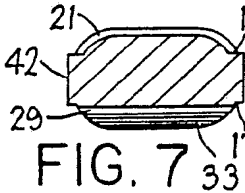


FIG. 7

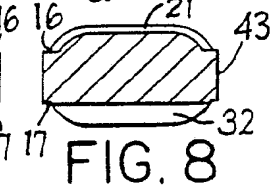


FIG. 8

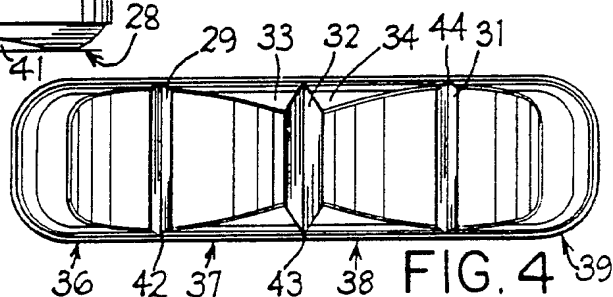


FIG. 4

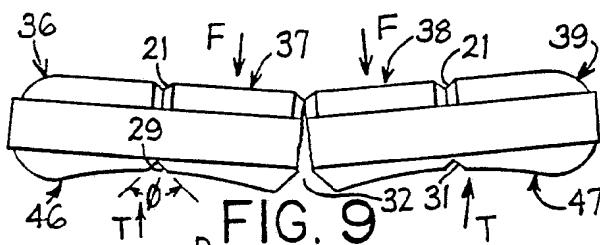


FIG. 9

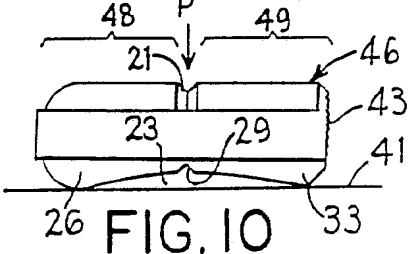


FIG. 10

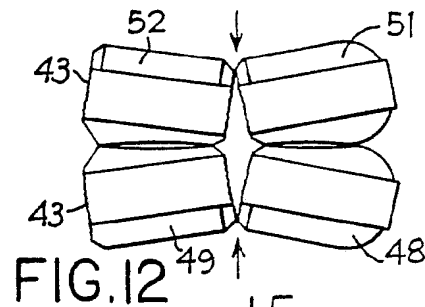


FIG. 12

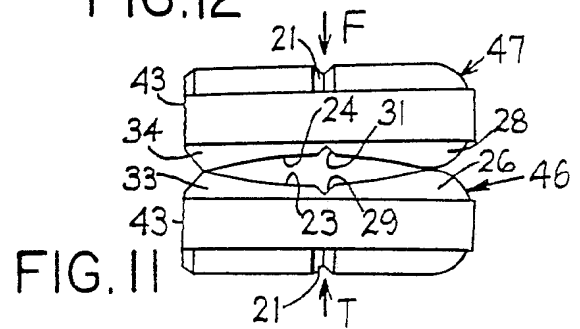


FIG. 11

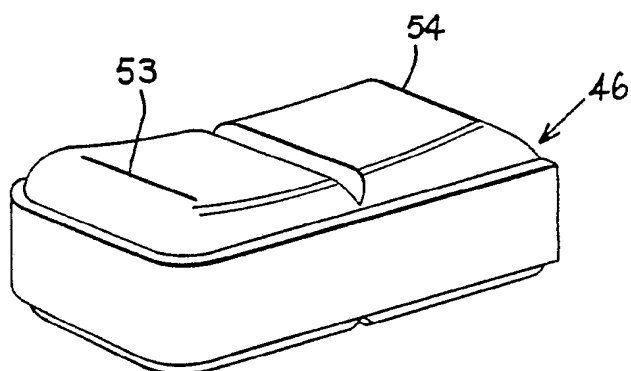


FIG. 13

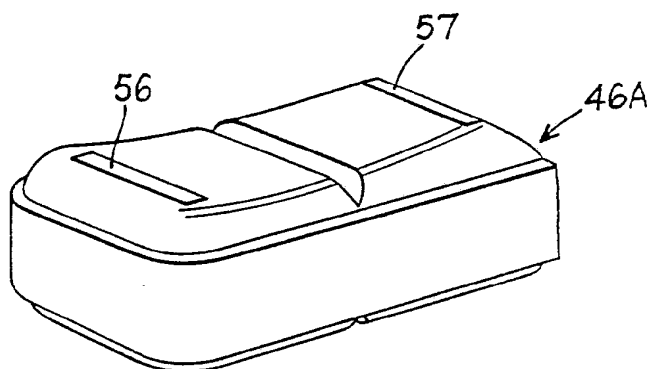


FIG. 14

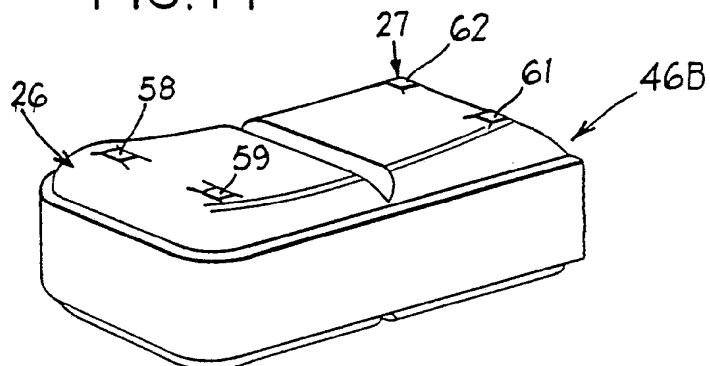



FIG. 15

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 88/04367

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply indicate all) ⁶		
According to International Patent Classification (IPC) or to both National Classification and IPC		
IPC ⁴ : A 61 J 3/10; A 61 K 9/44		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁷		
Classification System	Classification Symbols	
IPC ⁴	A 61 J; A 61 K	
Documentation Searched other than Minimum Documentation to the extent that such Documents are included in the Fields Searched ⁸		
III. DOCUMENTS CONSIDERED TO BE RELEVANT ⁹		
Category ¹⁰	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
A	DE, U, 8632046 (NOTTER) 12 March 1987 see claims 1-3; figures 1-9	1
	--	
A	US, A, 2052376 (ZELLERS) 25 August 1936 see page 2, left-hand column, lines 3-8; figure 5	1
	--	
A	GB, A, 2057878 (CIBA-GEIGY) 8 April 1981 see claims 1-6; figures	1
	--	
A	GB, A, 993291 (COOPER) 26 May 1965 see the whole document cited in the application	1

<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>¹⁰ * Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 45%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"Z" document member of the same patent family</p> </div> </div>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
14th March 1989	10. 04. 89	
International Searching Authority	Signature of Authorized Officer	
EUROPEAN PATENT OFFICE	 P.C.G. VAN DER PUTTEN	

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO.

US 8804367

SA 25947

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 05/04/89. The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
DE-U- 8632046	29-01-87	None	
US-A- 2052376		None	
GB-A- 2057878	08-04-81	BE-A- 884760	13-02-81
		FR-A, B 2462908	20-02-81
		DE-A- 3030622	26-03-81
		NL-A- 8004616	18-02-81
		JP-A- 56059708	23-05-81
		LU-A- 82718	24-03-81
		US-A- 4353887	12-10-82
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		SE-A- 8005759	17-02-81
		AU-B- 531058	11-08-83
		CA-A- 1158555	13-12-83
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		AT-B- 374366	10-04-84
		CH-A- 646330	30-11-84
GB-A- 993291		None	